



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,703	11/12/2003	Marlies Regiert	REGIERT ET AL-2	9249
25889	7590	02/23/2007	EXAMINER	
WILLIAM COLLARD COLLARD & ROE, P.C. 1077 NORTHERN BOULEVARD ROSLYN, NY 11576			ISSAC, ROY P	
			ART UNIT	PAPER NUMBER
			1623	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/23/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/712,703	REGIERT ET AL.	
	Examiner	Art Unit	
	Roy P. Issac	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 30 November 2006.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1 and 4-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 1 and 4-18 is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) 7 and 10 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date: _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date: _____	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

This application claims priority under 35 U.S.C § 119(e) to the provisional application, U.S. Patent Application Serial No.60/448,943 filed on February 20, 2003.

This Office Action is in response to Applicant's amendment/ remarks/ response filed 30 November, 2006, wherein claims 1, 12 and 14 have been amended and claims 2-3 have been cancelled, is acknowledged. Claims 1 and 4-18 are currently pending, and under examination on the merits.

Rejections Withdrawn

Applicant's arguments, see Pages 14, paragraphs 3 to page 20, paragraph 1, filed 30 November 2006, with respect to rejections under 35 U.S.C § 112, second paragraph with respect to recitation of the terms "substances which care for the skin," "humectant agents," "gel formers," "preservatives," "bactericides," "antioxidants," "sunscreen filters," "self-tanning agents," "additives," "auxillaries," "consistency-imparting agents," "fillers" "alcohol" "stabilizers" and "salts"" have been fully considered and are persuasive. The rejection of claim 8 under 35 U.S. C 112, paragraph 2, has been withdrawn.

Applicant's arguments, see Pages 20-21, filed 30 November 2006, with respect to the rejection(s) of claim(s) 1-3 and 6-10 under 102(b) over Wimmer et. al. have been fully considered and are persuasive. Therefore, the rejection has been withdrawn.

However, upon further consideration, a new ground(s) of rejection is made in view of the pending claims.

Applicant's arguments/ amendments, see Pages 21-22, filed 30 November 2006, with respect to the rejection(s) of claim(s) 1 and 9-10 under 102(b) over Qi et. al. have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the pending claims.

Applicant's arguments/amendments, see Pages 21-24, filed 30 November 2006, with respect to the rejection(s) of claim(s) 4-5, and 11-18 under 103(a) over Wimmer et. al. in view of one or more of the following publications, McCook et. al, Sauermann et. al., Boothroyd et. al., O'Prey et. al., Mohammadi et. al, Ferrari et. al., Dietz et. al., Lee et. al., Chevalier et al., Lee Vatter et. al., Fourman et. al., have been fully considered and are persuasive. Therefore, the rejections have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the pending claims.

Claim Objections

Claims 7 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 7 depends from claim 6 which in turn depends from claim 4. Claim 7 is directed to a mixture comprising

a complex selected from the group consisting of varying molar ratios of cyclodextrin and essential fatty acid as follows; 4:1, 3:1, 2:1 and 1:1. However, claim 4 is limited to complexes of ratios 3:1 and 4:1. As such, claim 7 is improperly broader than claim 4.

Applicant is advised that should claim 9 be found allowable, claim 10 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claim 10 claims the process as claimed in claim 9, which in itself is a process claim. Claim 10 does not add any limitations or otherwise further limit claim 9.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Lopez-Nicolas et. al. (Biochem. J. 1995, 308, 151-154; PTO-1449, Included by the applicant)

Lopez-Nicolas discloses compositions comprising complexes of cyclodextrin (CD) with linoleic acid. (Abstract). The inclusion complexes were disclosed as less

prone to autoxidation. (Page 151, Column 1, Paragraph 1, titled "Introduction"). The complexes were formed in the 1:2 stoichiometry of linoleic acid to beta-cyclodextrin. (Abstract; Page 152, Column 2, last paragraph to page 153, Column 1, first paragraph). The complexes were disclosed in a solution of sodium phosphate and sodium borate, which are considered preservatives and additives. The recitation "cosmetic or dermatological preparation" is considered the intended use of the claimed composition. Note that it is well settled that "intended use" of a composition or product, e.g., "cosmetic or dermatological preparation", will not further limit claims drawn to a composition or product, so long as the prior art discloses the same composition comprising the same ingredients in an effective amount, as the instantly claimed. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

As such, claims 1 and 8 are anticipated by Lopez-Nicolas et. al.

Claims 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Lajos Szente et. al. (*Journal of Inclusion Phenomena and Molecular Recognition Chemistry*, 16, 339-354, 1993; PTO-1449, Included by the applicant).

Lajos Szente et. al. discloses inclusion complexes of fatty acids with cyclodextrins. (Abstract). Complexes of fatty acid with beta-CD was disclosed to have stoichiometry of fatty acid to CD of 1:2 or 1:3. (Page 344, Paragraph 2; Table 1, Page 347). As discussed above, the recitations "cosmetic or dermatological preparation" is considered the intended use of the claimed composition. Claim 1 is deemed anticipated by Lajos Szente et. al.

Claims 1, 4, 6-7 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Bruzzese et. al. (EP 0470452; PTO-1449, Included by the applicant).

Bruzze et. al. discloses a method for the production of complexes of long chain polyunsaturated fatty acid with cyclodextrin. (Abstract; Column 3, paragraph 2). Bruzzese et. al. discloses a series of complexes of eicosapentaenoic acid and docosahexaenoic acid, both essential fatty acids, in 1:1, 1:1.25, 1:2 and 1:3 ratios. (Examples 1, 4, 5, 6, 7, 8, 9 and 10; Columns 4-7). Bruzzese further discloses complexes of cyclodextrin with linolenic acid. (Examples 11, and 13; Column 7).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bruzzese et. al. (EP 0470452; PTO-1449, Included by the applicant) in view of Schlenk et. al. (J. Am. Chem. Soc., 83, 2312-2320; 1961; PTO-892, Cited by the examiner).

The disclosure of Bruzzese et. al. is discussed above in the 102 rejection

Bruzze et. al. does not expressly disclose a 3:1 or 4:1 complex of alpha cyclodextrin with an essential fatty acid.

Schlenk et. al. discloses that fatty acids with 17 and higher carbons produce 1:3 complexes with cyclodextrins. (Page 2317, Column 2, paragraph 3, lines 10-20; Page 2315, Column 1, Figure 4). The figure indicate a relation between fatty acid chain length and the number of cyclodextrins in the complex. (Figure 4, right axis). The figure indicate a preference for alpha cyclodextrin to form higher order complexes. Schlenk et. al. indicates that the presence of cyclodextrins increase the solubility of fatty acids. (Page 2317, Column1, Paragraph 2). Note that most essential fatty acids are of chain lengths 15 and higher.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare complexes of essential fatty acids with cyclodextrins in the 3:1 or higher ratio because Burzzese disclose complexes of essential fatty acids with alpha, beta and gamma cyclodextrins and Schlenk et. al. disclose a chain length to complexation ratio in which alpha cyclodextrins forms higher order complexes.

One of ordinary skill in the art would have been motivated to use alpha cyclodextrins to form complexes with essential fatty acids because the complexation increases solubility and alpha cyclodextrin forms higher order complexes with longer chain fatty acids.

Therefore, one of ordinary skill in the art would have reasonably expected that the use of alpha cyclodextrin with one of the long chain essential fatty acid would have formed a complex of cyclodextrin and essential fatty acid in 3:1 or 4:1 ratio.

Thus the claimed invention as a whole is clearly *prima facie* obvious over the combined teachings of the prior art.

Claims 1 and 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable Wimmer et. al. (U.S. Patent No. 6,025,510, Feb, 2000; Of Record) in view of Lopez-Nicolas et. al. (Biochem. J. 1995, 308, 151-154; PTO-1449, Included by the applicant) further in view of Koulbanis et. al. (U.S. Patent No. 4,393,043; PTO-892, Cited by the examiner)

The '510 patent discloses the formation of complexes of cyclodextrin (CD) and vegetable oils that have high content of essential fatty acids, in particular linoleic acid and linolenic acid. (Column 3, lines 20-45 and Table 1). Note that linoleic acid and linolenic acid are considered essential fatty acids. Examples of complex formation between alpha, beta and gamma cyclodextrins are given in Example 1. (column 4, line 58 to Column 5, line 14). Example 11 shows the use of additives with cyclodextrin-evening primrose oil. (Column 8, lines 1 to 14). The weight ratio of vegetable oils and CD were disclosed as between 1:20 and 1:0.3. As the following calculations show, these ratios are within ranges claimed in the present invention.

The '510 patent discloses the composition of various fatty acids present in Evening primrose oil, Borage oil and Blackcurrant oil. Evening Primrose oil contains of 74.2% linoleic acid and 8-12% linolenic acid, both essential fatty acids. Borage oil contains 40.4% of linoleic acid and 19-25% of linolenic acid. Blackcurrant oil contains 48% linoleic acid and 30% linolenic acid. (Column 3, lines 20-40, Table 1).

The '510 patent further discloses the formation of oil and cyclodextrin complexes in weight ratios of 1:20 (oil:CD) and 1:0.3. These ratios when converted to molar ratios are as follows;

Molecular weight of α - Cyclodextrin: 972.8 g/mol

β - Cyclodextrin: 1135 g/mol

γ - Cyclodextrin: 1297.1 g/mol

Molecular weight of Linoleic acid: 280.45 g/mol

Linolenic acid: 278.4 g/mol

Molar ratio of linoleic acid in Evening primrose oil:

$$\frac{(74.2\% \times 1g)}{(280.45g/mol)} = 0.002646 \text{ mol/g}$$

Molar ratio of linolenic acid in Evening primrose oil:

$$\frac{(8 \text{ to } 12\% \times 1g)}{(278.4g/mol)} = (0.00029 \text{ to } 0.00043) \text{ mol/g}$$

Combined molar ratio of linoleic and linolenic acid in Evening primrose oil:

$$(0.00029 \text{ to } 0.00043) + 0.002646 = 0.002936 \text{ to } 0.003076 \text{ mol/g}$$

Similarly, the combined molar ratio of linoleic acid and linolenic acid in Borage oil was calculated to be 0.002123 to 0.002339 mol/g.

Similarly, the combined molar ratio of linoleic acid and linolenic acid in Blackcurrant oil was calculated to be 0.002789 mol/g.

Number of moles of α -CD in 1g of α - CD: $1g/972.8g/mol = 0.001$ moles.

Number of moles of β -CD in 1g of β -CD: $1g/1135g/mol = 0.000881$ moles.

Number of moles of γ - CD in 1g of β - CD: $1g/1297.1g/mol = 0.000771$ moles.

Reported weight ratio: 1:20 to 1:0.3 of Oil:CD (Column 3, lines 65-68)

Conversion of reported weight ratio of Oil:CD to molar ratio of Essential fatty acid: CD;

$$1:20 \quad 0.01:(20 \times 0.003076) = 0.01:0.062 = 1:6.2$$

$$1:0.3 \quad 0.01:(0.3 \times 0.003076) = 0.01:0.00093 = 1:0.093$$

Thus, the disclosed molar ratios of Essential fatty acids: α -CD are in the range of 1:0.093 to 1:6.2.

Example 7 discloses a complex of γ -CD and blackcurrant oil made with 22.5 g of oil and 104.3 g of CD. The molar ratio is calculated as follows;

$$\frac{104.3g \gamma\text{-CD}}{1297.1g/mol} = 0.08047 \text{ moles}$$

$$22.5g \text{ Oil} \times 0.002789 \text{ mol Essential Fatty Acid/g} = 0.0628 \text{ moles}$$

The molar ratio of essential fatty acids: γ -CD in example 7 is 1:1.28 which reads on "a mixture of these complexes" in claim 3 here. The mixtures of complexes in claim 6 and claim 7 also fall within the reported ratios of CD and oil. The weight reported weight ratios, 1:20 to 1:0.3 (Column 3, lines 65-68), are converted to molar ratios above, and found to be 1:6.2 to 1:0.093. The mixtures reported in claims 6 and 7 read on this range. The '510 patent further discloses the formation of oil-in-water emulsions with γ -CD and vegetable oils containing essential fatty acids. (Column 3 line 42 to Column 4, line 12). The complex is formed at a temperature range between 20-60°C and by mixing for a period between an hour and few days (Column 4, lines 6-11). The '510 patent also describes the composition therein further comprising antioxidants, vitamins, preservatives, self-tanning additives, thickeners, silicone oils, and fillers as claimed. (Column 4, lines 25-28).

The '510 patent does not expressly disclose complexes of free essential fatty acids that are not in the form of triglycerides.

The disclosure of Lopez-Nicolas is disclosed above.

Koulbanis et. al. discloses the use of vitamin F for the preparation of cosmetics. (Column 1, Paragraph 1). Koulbanis et. al. discloses vitamin F as useful for the treatment of skin dryness. (Column 1, lines 27-30). Koulbanis et. al. further disclose that the use of vitamin F is limited by problems with oxidation. (Column 1, lines 30-35). Koulbanis further discloses several emulsions comprising vitamin F compounds and oil by mixing the ingredients. (Columns 5-6; Examples II-XII). Note that the preparation of

a dispersion before the formation of an emulsion is considered a routine step within the capabilities of one skill in the art in the cosmetic art.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a cosmetic composition comprising an essential fatty acid complexed with a cyclodextrin in one of 1:1 or 1:2 or 1:3 or 1:4 ratios because, triglycerides comprising essential fatty acids in the particular ratios claimed herein, as well as the free essential fatty acids themselves are well known for their use in cosmetic formulations, and the complexes formed between essential fatty acids and well known to reduce oxidation of essential fatty acids.

One of ordinary skill in the art would have been motivated to use complexes of essential fatty acids with cyclodextrins in one of the 1:1 or 1:2 or 1:3 or 1:4 ratios for use in a cosmetic preparation because essential fatty acids, well known for use in cosmetics in their free acid form and as triglycerides, are known to be prone to oxidation and the complexation with cyclodextrins in the particular ratios claimed herein is well known to reduce oxidation.

Therefore, one of ordinary skill in the art would have reasonably expected that the use of a complex of an essential fatty acid with cyclodextrin in a cosmetic composition would have had similar or better effect in the preparation of the cosmetic.

Thus the claimed invention as a whole is clearly *prima facie* obvious over the combined teachings of the prior art.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wimmer et. al (U.S. Patent No. 6,025,510; Of Record), in view of Lopez-Nicolas et. al. (Biochem. J. 1995, 308, 151-154; PTO-1449, Included by the applicant) further in view of Koulbanis et. al. (U.S. Patent No. 4,393,043; PTO-892, Cited by the examiner) further in view of McCook et. al. (U.S. Patent No. 5,690,948; PTO-892, Of Record) and Sauermann et. al. (U.S. Patent No. 5,710,177; Of Record).

The disclosure of the '510 patent is discussed above.

The '510 patent does not expressly disclose complexes of free essential fatty acids that are not in the form of triglycerides or the use of octyl palmitate, octyl stearate, polyglycerol-2 sesquiosstearate, cyclomethicone or dimethiconol, lauryl diemthicone, cyclomethicone, titanium dioxide, polymethylsilsequioxane, zinc oxide, glycerol, sodium chloride.

The disclosure of Lopez-Nicolas is discussed above.

The disclosure of Koulbanis et. al. is discussed above.

McCook et. al discloses skin care products comprising, octyl palmitate, octyl stearate (Column 19, Example 9B), dimethicone, dimethicanol, cyclomethicone, titanium dioxide (Column 18, Example 6), glycerol (Column 5, lines 5-10), sodium chloride. (Column 20, Example 9E), and Tospearl (Column 5, lines 8-13). Note that polymethylsilsequioxane is known by its trade name Tospearl. (GE catalog, Page 3, last column; PTO-892, Cited by the examiner).

Saurmann et. al discloses the use of zinc oxide in personal care products. (Column 5, lines 3-8).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a cosmetic composition of Claim 11 because complexes of cyclodextrin with essential fatty acids in their acid form and in their triglyceride form are well known for their use in cosmetic compositions, and the complexation is well known to increase the stability of essential fatty acids, and other particular ingredients claimed herein are well known for their use in cosmetic formulations and are choosing the particular ingredients is a routine step within the capabilities of one of skill in the art. It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

One of ordinary skill in the art would have been motivated to use complexes of essential fatty acids with cyclodextrins in one of the 1:1 or 1:2 or 1:3 or 1:4 ratios for use in a cosmetic preparation because essential fatty acids, well known for use in cosmetics in their free acid form and as triglycerides, are known to be prone to oxidation and the complexation with cyclodextrins in the particular ratios claimed herein is well known to reduce oxidation.

Therefore, one of ordinary skill in the art would have reasonably expected that the use of a complex of an essential fatty acid with cyclodextrin in a cosmetic composition would have had similar or better effect in the preparation of the cosmetic.

Thus the claimed invention as a whole is clearly *prima facie* obvious over the combined teachings of the prior art.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wimmer et. al (U.S. Patent No. 6,025,510; Of Record), in view of Lopez-Nicolas et. al. (Biochem. J. 1995, 308, 151-154; PTO-1449, Included by the applicant) further in view of Koulbanis et. al. (U.S. Patent No. 4,393,043; PTO-892, Cited by the examiner) in view of McCook et. al. (U.S. Patent No. 5,690,948; Of Record) and Boothroyd et. al (U.S. Patent No. 5,250,289; Of Record) and O'Prey et. al. (Of Record).

Disclosure of the '510 patent is discussed above.

The '510 patent does not expressly disclose complexes of free essential fatty acids that are not in the form of triglycerides or the use of kathon, Hostacerin and Beeswax.

The disclosure of Lopez-Nicolas is discussed above.

The disclosure of Koulbanis et. al. is discussed above.

The disclosure of McCook et. al. is disclosed above.

The '289 patent discloses the use of kathon, hostacerin and beeswax in sunscreen compositions. (Example 4, Column 4, lines 35-53).

O'Prey et. al discloses the use of Belsil in cosmetic compositions. (Page 26, lines 15-20).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a cosmetic composition of Claim 12 because complexes of cyclodextrin with essential fatty acids in their acid form and in their triglyceride form are well known for their use in cosmetic compositions, and the complexation is well known

to increase the stability of essential fatty acids, and other particular ingredients claimed herein are well known for their use in cosmetic formulations and choosing the particular ingredients is considered a routine step within the capabilities of one of skill in the art. It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

One of ordinary skill in the art would have been motivated to use complexes of essential fatty acids with cyclodextrins in one of the 1:1 or 1:2 or 1:3 or 1:4 ratios for use in a cosmetic preparation because essential fatty acids, well known for use in cosmetics in their free acid form and as triglycerides, are known to be prone to oxidation and the complexation with cyclodextrins in the particular ratios claimed herein is well known to reduce oxidation.

Therefore, one of ordinary skill in the art would have reasonably expected that the use of a complex of an essential fatty acid with cyclodextrin in a cosmetic composition would have had similar or better effect in the preparation of the cosmetic.

Thus the claimed invention as a whole is clearly *prima facie* obvious over the combined teachings of the prior art.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wimmer et. al (U.S. Patent No. 6,025,510; Of Record), in view of Lopez-Nicolas et. al. (Biochem. J. 1995, 308, 151-154; PTO-1449, Included by the applicant) further in view of

Koulbanis et. al. (U.S. Patent No. 4,393,043; PTO-892, Cited by the examiner) in view of McCook et. al. (U.S. Patent No. 5,690,948; Of Record), and Mohammadi et. al. (U.S. Patent No. 6,649,178; Of Record).

The '510 patent does not expressly disclose complexes of free essential fatty acids that are not in the form of triglycerides or the use of cetyl alcohol or mineral oil or stearic acid or allantoin or propylene glycol or phenyltrimethicone.

The disclosure of Lopez-Nicolas is discussed above.

The disclosure of Koulbanis et. al. is discussed above.

The disclosure of McCook et. al. is disclosed above. McCook et. al further discloses skin care products comprising, cetyl alcohol (Example 6, Column 17), stearic acid (Column 19, Example 8), propylene glycol (Column 19, Example 9B), water (Column 19, Example 9B).

Mohammadi et. al discloses the use of mineral oil (Column 3, lines 37-43), allantoin (Column 7, Table 1, line 17) and phenyltrimethicone (Column 4, lines 3-9).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a cosmetic composition of Claim 13 because complexes of cyclodextrin with essential fatty acids in their acid form and in their triglyceride form are well known for their use in cosmetic compositions, and the complexation is well known to increase the stability of essential fatty acids, and other particular ingredients claimed herein are well known for their use in cosmetic formulations and are choosing the particular ingredients is a routine step within the capabilities of one of skill in the art. It has been held that it is within the skill in the art to select optimal parameters, such as

amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

One of ordinary skill in the art would have been motivated to use complexes of essential fatty acids with cyclodextrins in one of the 1:1 or 1:2 or 1:3 or 1:4 ratios for use in a cosmetic preparation because essential fatty acids, well known for use in cosmetics in their free acid form and as triglycerides, are known to be prone to oxidation and the complexation with cyclodextrins in the particular ratios claimed herein is well known to reduce oxidation.

Therefore, one of ordinary skill in the art would have reasonably expected that the use of a complex of an essential fatty acid with cyclodextrin in a cosmetic composition would have had similar or better effect in the preparation of the cosmetic.

Thus the claimed invention as a whole is clearly *prima facie* obvious over the combined teachings of the prior art.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wimmer et. al (U.S. Patent No. 6,025,510; Of Record), in view of Lopez-Nicolas et. al. (Biochem. J. 1995, 308, 151-154; PTO-1449, Included by the applicant) further in view of Koulbanis et. al. (U.S. Patent No. 4,393,043; PTO-892, Cited by the examiner) in view of McCook et. al. (U.S. Patent No. 5,690,948; Of Record), and Ferrari et.al (U.S. Patent No. 6,811,770; Of Record).

The '510 patent does not expressly disclose complexes of free essential fatty acids that are not in the form of triglycerides or the use of carbopol, glycerol, triethanolamine, stearic acid, isopropyl myristate, nexbae, arlacet, cetyl alcohol, Belsil and BHT.

The disclosure of Lopez-Nicolas is discussed above.

The disclosure of Koulbanis et. al. is discussed above.

The disclosure of McCook et. al. is disclosed above.

Ferrari et. al. discloses the use of polydecenes, (Column 9, lines 1-10), and Belsil (Column 16, lines 55-65), and Arlacel (Column 19, lines 5-15). Note that Nexbase is the tradename for polydecenes. (Lohman et. al. PTO-892; Cited by the examiner).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a cosmetic composition of Claim 14 because complexes of cyclodextrin with essential fatty acids in their acid form and in their triglyceride form are well known for their use in cosmetic compositions, and the complexation is well known to increase the stability of essential fatty acids, and other particular ingredients claimed herein are well known for their use in cosmetic formulations and are choosing the particular ingredients is a routine step within the capabilities of one of skill in the art. It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

One of ordinary skill in the art would have been motivated to use complexes of essential fatty acids with cyclodextrins in one of the 1:1 or 1:2 or 1:3 or 1:4 ratios for use

in a cosmetic preparation because essential fatty acids, well known for use in cosmetics in their free acid form and as triglycerides, are known to be prone to oxidation and the complexation with cyclodextrins in the particular ratios claimed herein is well known to reduce oxidation.

Therefore, one of ordinary skill in the art would have reasonably expected that the use of a complex of an essential fatty acid with cyclodextrin in a cosmetic composition would have had similar or better effect in the preparation of the cosmetic.

Thus the claimed invention as a whole is clearly *prima facie* obvious over the combined teachings of the prior art.

Claims 15-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wimmer et. al (U.S. Patent No. 6,025,510; Of Record), in view of Lopez-Nicolas et. al. (Biochem. J. 1995, 308, 151-154; PTO-1449, Included by the applicant) further in view of Koulbanis et. al. (U.S. Patent No. 4,393,043; PTO-892, Cited by the examiner) in view of Dietz et. al. (U.S. Patent No. 7,074,419; Of Record) and Lee et. al (U.S. Patent No. 6,908,625; Of Record).

The '510 patent does not expressly disclose complexes of free essential fatty acids that are not in the form of triglycerides or the use of stearyl glucoside, glyceryl stearate, stearyl alcohol, decyl cocoate, cetearyl ethylhexanoate and glycerol.

The disclosure of Lopez-Nicolas is discussed above.

The disclosure of Koulbanis et. al. is discussed above.

The '419 patent discloses skin care compositions comprising glyceryl stearate, stearyl alcohol, glycerol, (Column 13, Example 7), and decyl cocoate. (Column 12, Example 4) and avocado oil (Column 12, Example 4), lactic acid (Column 9, lines 20-25), caprylic/capric triglyceride. (Column 16, Cream 2: lines 15-25) and ethylhexyl stearate. (Column 16, lines 55-65; Cream 2).

The '625 patent discloses skin care compositions comprising stearyl glucoside. (Column 7, Table 4).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a cosmetic composition of Claims 15-16 because complexes of cyclodextrin with essential fatty acids in their acid form and in their triglyceride form are well known for their use in cosmetic compositions, and the complexation is well known to increase the stability of essential fatty acids, and other particular ingredients claimed herein are well known for their use in cosmetic formulations and are choosing the particular ingredients is a routine step within the capabilities of one of skill in the art. It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

One of ordinary skill in the art would have been motivated to use complexes of essential fatty acids with cyclodextrins in one of the 1:1 or 1:2 or 1:3 or 1:4 ratios for use in a cosmetic preparation because essential fatty acids, well known for use in cosmetics in their free acid form and as triglycerides, are known to be prone to oxidation and the

complexation with cyclodextrins in the particular ratios claimed herein is well known to reduce oxidation.

Therefore, one of ordinary skill in the art would have reasonably expected that the use of a complex of an essential fatty acid with cyclodextrin in a cosmetic composition would have had similar or better effect in the preparation of the cosmetic.

Thus the claimed invention as a whole is clearly *prima facie* obvious over the combined teachings of the prior art.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wimmer et. al (U.S. Patent No. 6,025,510; Of Record), in view of Lopez-Nicolas et. al. (Biochem. J. 1995, 308, 151-154; PTO-1449, Included by the applicant) further in view of Koulbanis et. al. (U.S. Patent No. 4,393,043; PTO-892, Cited by the examiner) in view of Chevalier et. al. (U.S. Patent No. 6,284,281; PTO-892, Of Record), Lee Vatter et. al. (U.S. Patent No. 6,224,888; Of Record), Fourman et. al (U.S. Patent No. 4559225; PTO-892, Cited by the examiner) and Aust et. al. (U.S. Patent Publication No. 2003/0228267; PTO-892, Cited by the examiner).

The '510 patent does not expressly disclose complexes of free essential fatty acids that are not in the form of triglycerides or the use of white beeswax, polyglyceryl-2 sesquioisostearate, octyl dimethicone or ethoxy glucoside or cyclomethicone, trimethyl siloxysilicate, iron oxide, talc, titanium dioxide, sodium chloride, and γ -cyclodextrin- α -tocopherol complex and methylchloroisothiazolinone.

The disclosure of Lopez-Nicolas is discussed above.

The disclosure of Koulbanis et. al. is discussed above.

The '888 patent discloses the use of cyclomethicone (Column 18, lines 29-50; Example VIII), sodium chloride (Column 21, lines 1-30), talc and iron oxide in cosmetic preparations. (Column 11, lines 45-50).

The '281 patent discloses the use of polyglyceryl-2 sesquioctostearate for the formation of emulsions in cosmetic compositions. (Column 4, lines 24-35). The '281 patent further discloses the use of water in cosmetic combinations. (Column 6, Example 1).

Aust et. al discloses the use of methylthiazolinone and titanium dioxide in cosmetic compositions.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a cosmetic composition of Claim 17 because complexes of cyclodextrin with essential fatty acids in their acid form and in their triglyceride form are well known for their use in cosmetic compositions, and the complexation is well known to increase the stability of essential fatty acids, and other particular ingredients claimed herein are well known for their use in cosmetic formulations and are choosing the particular ingredients is a routine step within the capabilities of one of skill in the art. It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

One of ordinary skill in the art would have been motivated to use complexes of essential fatty acids with cyclodextrins in one of the 1:1 or 1:2 or 1:3 or 1:4 ratios for use

in a cosmetic preparation because essential fatty acids, well known for use in cosmetics in their free acid form and as triglycerides, are known to be prone to oxidation and the complexation with cyclodextrins in the particular ratios claimed herein is well known to reduce oxidation.

Therefore, one of ordinary skill in the art would have reasonably expected that the use of a complex of an essential fatty acid with cyclodextrin in a cosmetic composition would have had similar or better effect in the preparation of the cosmetic.

Thus the claimed invention as a whole is clearly *prima facie* obvious over the combined teachings of the prior art.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wimmer et. al (U.S. Patent No. 6,025,510; Of Record), in view of Lopez-Nicolas et. al. (Biochem. J. 1995, 308, 151-154; PTO-1449, Included by the applicant) further in view of Koulbanis et. al. (U.S. Patent No. 4,393,043; PTO-892, Cited by the examiner) in view of Carola et. al. (U.S. Patent Publication No. 2004/0067894 A1, filed Sep. 23, 2003; Of Record).

The '510 patent does not expressly disclose complexes of free essential fatty acids that are not in the form of triglycerides or the use of glycerol monomyristate, stearic acid, cetyl alcohol, isopropyl palmitate and methylparaben in a cosmetic formulation.

The disclosure of Lopez-Nicolas is discussed above.

The disclosure of Koulbanis et. al. is discussed above.

Carola et. al. discloses the use of glyceryl monomyristate, and cetyl alcohol (Page 11, Columns 1-2, Paragraph 167), stearic acid, and methyl paraben. (Page 18, Columns 1-2, Paragraph 242, Table 2), isopropyl palmitate (Page 8, Column 2, Paragraph 125).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a cosmetic composition of Claim 18 because complexes of cyclodextrin with essential fatty acids in their acid form and in their triglyceride form are well known for their use in cosmetic compositions, and the complexation is well known to increase the stability of essential fatty acids, and other particular ingredients claimed herein are well known for their use in cosmetic formulations and are choosing the particular ingredients is a routine step within the capabilities of one of skill in the art. It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

One of ordinary skill in the art would have been motivated to use complexes of essential fatty acids with cyclodextrins in one of the 1:1 or 1:2 or 1:3 or 1:4 ratios for use in a cosmetic preparation because essential fatty acids, well known for use in cosmetics in their free acid form and as triglycerides, are known to be prone to oxidation and the complexation with cyclodextrins in the particular ratios claimed herein is well known to reduce oxidation.

Therefore, one of ordinary skill in the art would have reasonably expected that the use of a complex of an essential fatty acid with cyclodextrin in a cosmetic composition would have had similar or better effect in the preparation of the cosmetic.

Thus the claimed invention as a whole is clearly *prima facie* obvious over the combined teachings of the prior art.

No claim is allowed. This rejection is made NON-FINAL due to the new/modified grounds of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy P. Issac whose telephone number is 571-272-2674. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Roy P. Issac
Patent Examiner
Art Unit 1623


S. Anna Jiang, Ph.D.
Supervisory Patent Examiner
Art Unit 1623